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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 259/012 6224 09/713,749 11/14/2000 Daniel M. LaFontaine **EXAMINER** 7590 07/14/2004 David T. Burse FARAH, AHMED M Bingham McCutchen LLP ART UNIT PAPER NUMBER Three Embarcadero Center Suite 1800 3739 San Francisco, CA 94111-4067

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	_	
Office Action Summary		09/713,749	LAFONTAINE ET AL.		
		Examiner	Art Unit		
		Ahmed M Farah	3739		
	The MAILING DATE of this communicat				
Period fo	• •				
THE - Exte after - If the - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR MAILING DATE OF THIS COMMUNICA asions of time may be available under the provisions of 37 SIX (6) MONTHS from the mailing date of this communical period for reply specified above is less than thirty (30) day of period for reply is specified above, the maximum statutor are to reply within the set or extended period for reply will, the reply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b).	TION. CFR 1.136(a). In no event, however, may atton. ys, a reply within the statutory minimum of y period will apply and will expire SIX (6) No ystatute, cause the application to become	a reply be timely filed thirty (30) days will be considered timely. ONTHS from the mailing date of this communication. ABANDONED (35 U.S.C. § 133).		
Status					
1) 🛛	Responsive to communication(s) filed o	n 25 March 2004.			
2a)□	_	☐ This action is non-final.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.				
Disposit	ion of Claims				
4)⊠	4) Claim(s) <u>64-70,72-79 and 81-87</u> is/are pending in the application.				
•	4a) Of the above claim(s) <u>64-69 and 77</u> is/are withdrawn from consideration.				
	Claim(s) is/are allowed.				
6)⊠	☑ Claim(s) <u>70,72-75,79,81,82 and 85-87</u> is/are rejected.				
7)⊠	☑ Claim(s) <u>76,78,83 and 84</u> is/are objected to.				
8)[8) Claim(s) are subject to restriction and/or election requirement.				
Applicat	ion Papers	·			
9)[The specification is objected to by the Ex	kaminer.			
10)[10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.				
•	Applicant may not request that any objection	to the drawing(s) be held in abe	ance. See 37 CFR 1.85(a).		
	Replacement drawing sheet(s) including the	·			
11)	The oath or declaration is objected to by	the Examiner. Note the attach	ed Office Action or form PTO-152.		
Priority (ınder 35 U.S.C. § 119				
12)	Acknowledgment is made of a claim for	foreign priority under 35 U.S.C	. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:					
	1. Certified copies of the priority documents have been received.				
	2. Certified copies of the priority doc	uments have been received in	Application No		
	3. Copies of the certified copies of the	ne priority documents have be	en received in this National Stage		
	application from the International	, , , , , , , , , , , , , , , , , , , ,			
* 5	See the attached detailed Office action fo	r a list of the certified copies n	ot received.		
Attachmen	t(s)	•			
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Notice of Informal Patent Application (PTO-152)					
	mation Disclosure Statement(s) (PTO-1449 or PTC er No(s)/Mail Date	6) Other:			

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DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claims 70 and 72-75 are withdrawn in view of the newly discovered reference(s) to Geddess et al. U.S. Patent No. 4,979,948. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

- The following is a quotation of the appropriate paragraphs of 35 U.S.C.
 that form the basis for the rejections under this section made in this Office action:
 - A person shall be entitled to a patent unless -
 - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 79, 81, 82, 86, and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Qian U.S. Patent No. 5,047,028.

Qian discloses apparatus and method for creating thrombosis of vessel under the surface of a body cavity, the method comprising the steps of:

inserting the distal portion of tubular member 10 into the patient's body, the distal portion comprising an expandable member (balloon 12) in a collapsed condition (see the abstract; Col. 1, lines 18-23; Col. 2, lines 8-10; and claim 1), and an electrode (conducting wire 16 connected to an external electrode 20) within an interior space of the expandable member;

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positioning the distal portion of the tubular member proximate a target site (Col. 2, lines 10-11);

directing electrolyte fluid through the lumen of the tubular member and into the interior space of the expandable member (Col. 2, lines 11-15); and energizing the electrode with electrical energy, thereby transferring electrical energy from the electrode through the expandable member via the electrolyte fluid to ablate the target site (see claim 9),

wherein the expandable member comprises a plurality of perforations (semi-permeable wall) through which the electrolyte fluid flows to the target site (Col. 2, lines 15-19).

In this Office Action, the word **ablation** is defined as 'the surgical excision or amputation of body part or tissue by cutting, <u>heating/coagulating</u>, and/or removing body tissue using mechanical (i.e., ultrasound), electrical and/or optical energy. This interpretation is in line with the common use of the word 'ablation' in the relevant art.

Furthermore, The American Heritage Dictionary of the English Language defines the word **ablate** as "to remove by erosion, meting, evaporation, or vaporization." See the attached page marked **Exhibit 1**. These terms define a process of transformation of (a liquid or sol, for example) into or as if into a soft,

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semisolid, or solid mass,¹ i.e., coagulation. Therefore, Qian teaches a method for ablating body tissue as presently claimed.

Furthermore, the word **thrombosis** is defined as "the formation, presence, or development of a thrombus (A fibrinous <u>clot</u> formed in a blood vesselⁱ); the word **clot** is defined as "a thick, viscous, or <u>coagulated</u> mass or lump, as of blood; iii and the word **coagulate** is defined as 'the phase transformation of (a liquid or sol, for example) into a soft, semisolid or solid mass, which results from heating or cooling the mass (a biological tissue in this case).' Hence, since thromboses results from a coagulated/ablated tissue, Qian teaches a method for ablating body tissue.

As to claim 81, the expandable member (balloon 12) of Qian is expanded as the electrolytic fluid is directed into its interior space (Col. 2, lines 13-15).

As to claims 86 and 87, the catheter of Qian is configured to be inserted into a blood vessel. Therefore, it is inherent that catheters designed for use in blood vessels are essentially flexible.

4. Claims 70, 72-75, and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Geddess et al. U.S. Patent No. 4,979,948.

Geddess et al. teaches method and apparatus for thermally destroying a layer of an organ, the apparatus comprising:

¹ The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Electronic version licensed from INSO Corporation; United States. All rights reserved.

a catheter 100 having a proximal end attachable to electrolytic solution, a distal portion sized for insertion of a patient's body (see Fig. 1), and a lumen 103 for delivering fluid from the proximal portion to the distal end;

an expandable member 114 disposed on the distal portion of the catheter and configured to conform and make contact with the body being treated (the distal end of the expandable member takes the shape of the body being treated. For example, if the body being treated is substantially flat, the expandable member takes a substantially planer distal end); and

an RF electrode 104/103 positioned on the distal end of the catheter and communicating with the lumen, the electrode configured for coupling to an external RF source as presently claimed.

The phrase "whereby RF energy may be transferred from the electrode to the selected are ... " in claim 70 is an intended use and therefore not given a patentable weigh. If applicants desire the recited elements to be considered, they must positively recite the limitations within the body of the claim.

As to claim 75, the electrode comprises a plurality of apertures 108, the apertures allowing electrolyte solution to pass into the interior space of the expandable member.

Allowable Subject Matter

5. Claims 76, 78, 83, and 84 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

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6. Any inquiry concerning this communication or earlier communications from

the examiner should be directed to Ahmed M Farah whose telephone number is

(703) 305-5787. The examiner can normally be reached on Mon-Thur. 9:30 AM-

7:30 PM, and 9:30 AM - 6:30 PM on every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Linda C.M DVorak can be reached on (703) 308-0994.

The fax phone number for the organization where this application or proceeding

is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from

the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public

PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-

free).

A. Farah

Patent Examiner, AU 3739

Exhibit A

ab·late

ab·late (□·bl□t□) verb
ab·lat·ed, ab·lat·ing, ab·lates verb, transitive
To remove by erosion, melting, evaporation, or vaporization.

verb, intransitive
To become ablated; undergo ablation.

[Back-formation from ablation.]

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